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Evaluation of Linearity Air Kerma Applied to the IEC 60601-2-45 Standard in Mammographic X-ray

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유방촬영용 X선 진단장치에서 IEC 60601-2-45 표준규격을 적용한 직선성 평가

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Abstract The quality control items of mammography devices in South Korea do not include the linearity, which is required by international standards. The linearity is a requirement for the adjustment of radiation dose and radiation quality. This study tested the linearity, which was suitable for the IEC 60601-2-45 standard, of the 5 mammography devices. All showed adequate results. Consistent measurement management is required for more developed quality control in the future.

Key Words : IEC 60601-2-45 Standard, Linearity, Mammography device, Quality control

요 약 현재 우리나라 유방촬영장치의 정도관리 항목에는 국제규격에서 원하는 직선성이 빠져있다. 직선성은 방사선량 및 방사선질의 조정을 위한 요구사항이다. 본 연구에서는 유방촬영장치 5대를 대상으로 IEC 60601-2-45 규격에 맞는 직선성을 시험한 결과 모두 적합한 결과를 보였으며 앞으로 좀 더 발전된 정도관리를 위해서는 지속적인 측정관리가 필요하다.

주제어 : IEC 60601-2-54 표준규격, 직선성, 유방촬영장치, 정도관리

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1. Introduction

International institutions have developed quality and performance management programs for the installation and use of radiation generators used in disease diagnosis. South Korea has had limited test conditions or test methods according to the Ministry of Health and Welfare. Pre-quality management and post-performance management were realized with the “regulation for safety management of diagnosis radiation generators,” which was legislated in 1995 by the Korea Food and Drug Administration [1].

The radiation generators used in medical centers have routine inspections every 3 years according to the regulations for safety management, and are strictly regulated with the suspension of use for inconsistencies [2]. Therefore, performance management and quality management of generators should be accomplished in accordance with the regulations for safety management of The Ministry of Health and Welfare law for radiation generators [3][4][5]. Routine inspection is required with quality control items. However, the quality control items used in Korea have a slight difference compared to items used for international standards.

IEX 60601-2-45 has particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices, and to evaluate the linearity of air kerma over the intervals of limited loading conditions among normal requirements for radiation levels and radiation quality controls [6][7]. This linearity not only helps to control important X-ray levels for both patients and the quality of images, but helps to show the degree of character reproduction sequentially, even in long-term use [8].

The IEC standard is valid for enforcing the quality management of devices, since it uses an internationally certified test method and items. However, inspection agencies enforcing quality management in Korea only enforce it partially.

Therefore, this research proposes a direction of improvement in quality management inspection for future mammographic devices that measure and comparably evaluate the linearity from evaluation items of mammographic diagnosis devices, and evaluates the performance evaluation from post-management items and uses its data.

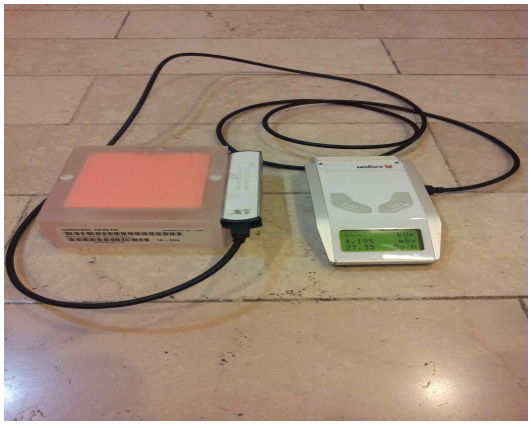
2. Materials and Methods

2.1 Materials

Five CR devices and DR devices were targeted, and a Raysafe Xi dosimeter was used to measure the air kerma and linearity of mammographic generators according to IEC 60601-2-45 (Fig 1).

The mammographic X-ray equipment used is as follows:

- LORAD AFFINITY (Hologic inc.)
- LORAD VARIAN (Hologic inc.)
- NOVATION MAMMOMAT (Siemens inc.)
- ALPHA ST MGF-101 (GE inc.)



[Fig. 1] Measurement tools

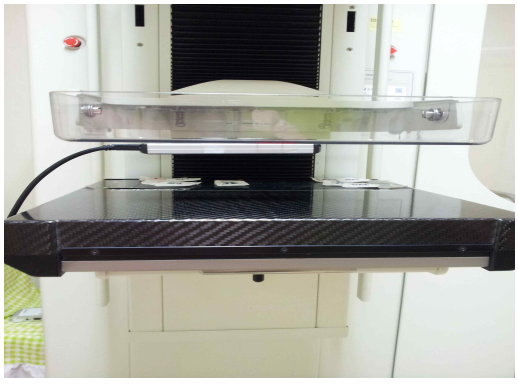
2.2 Methods of linearity

The measurement method used 10 loads for each selected mAs set-up and measuring air kerma in a

fixed area at over 40 mm from a patient (Fig 2). The average of air kerma from each of ten measurements was calculated (1), and it was determined whether the value matches with the equation.

$$\left|\frac{\overline{K_1}}{Q_1}-\frac{\overline{K_2}}{Q_2}\right| \le 0.2\,\frac{\frac{\overline{K_1}}{Q_1}+\frac{\overline{K_2}}{Q_2}}{2} \qquad (1)$$

The variables of air kerma measurement values should have an accuracy of 0.2 or higher for changes of the selected mAs from all mAs linearly.



[Fig. 2] Air kerma measurements

The measurement of suitability was enforced at 30 kvp, and the mAs setup for testing of the low value of the first pair corresponded to the minimum mAs setup. The set point proportion of the selected mAs of each pair should be close to 2 if possible, but must not exceed 2. The high value of mAs setup for each pair to be measured should be low for the next pair of mAs setups. The value of the maximum condition should correspond with the maximum mAs setup, and the low value should be half for the next value while corresponding to the half or maximum mAs setup.

3. Results and Discussion

3.1 Results

Five mammographic X-ray devices were applied to IEC 60601-2-45, and the linearity of air kerma over the interval of limited load conditions was evaluated (Tables 1-5).

<Table 1> Linearity of first equipment

Equipment	KV	mAs	Mean (mGy)	mGy /mAs	Linearity	Evaluation
No.1	30	4	0.72	0.180	0.004≤0.036	conformity
	30	6	1.10	0.184	0.002≤0.037	conformity
	30	12	2.23	0.186	0.001≤0.037	conformity
	30	20	3.74	0.187	0.000≤0.037	conformity
	30	40	7.50	0.188	0.000≤0.037	conformity
	30	80	15.05	0.188	0.000≤0.038	conformity
	30	150	28.16	0.188	0.001≤0.037	conformity
	30	300	37.81	0.189		*
	30	200	56.44	0.188	0.000≤0.037	conformity
	30	400	75.33	0.188		*

* Blank for the maximum mAs setup and corresponded value setup

<Table 2> Linearity of second equipment

Equipment	KV	mAs	Mean (mGy)	mGy /mAs	Linearity	Evaluation
No.2	30	2	0.35	0.173	0.000≤0.035	conformity
	30	4	0.69	0.173	0.002≤0.035	conformity
	30	8	1.40	0.175	0.000≤0.035	conformity
	30	16	2.80	0.175	0.001≤0.035	conformity
	30	32	5.62	0.176	0.001≤0.035	conformity
	30	63	11.12	0.176	0.001≤0.035	conformity
	30	125	22.13	0.177	0.000≤0.035	conformity
	30	250	44.36	0.177	0.000≤0.036	conformity
	30	500	88.86	0.178		*

* Blank for the maximum mAs setup and corresponded value setup

<Table 3> Linearity of third equipment

Equipment	KV	mAs	Mean (mGy)	mGy /mAs	Linearity	Evaluation
No.3	30	4	0.58	0.144	0.014≤0.030	conformity
	30	8	1.26	0.158	0.016≤0.030	conformity
	30	16	2.28	0.142	0.000≤0.028	conformity
	30	30	4.26	0.142	0.001≤0.028	conformity
	30	60	8.46	0.141	0.006≤0.029	conformity
	30	120	17.70	0.148	0.006≤0.029	conformity
	30	240	33.88	0.141		*
	30	250	35.87	0.143	0.016≤0.027	conformity
	30	500	63.61	0.127		*

* Blank for the maximum mAs setup and corresponded value setup

<Table 4> Linearity of fourth equipment

Equipment	KV	mAs	Mean (mGy)	mGy /mAs	Linearity	Evaluation
No.4	30	4	0.55	0.138	0.007≤0.028	conformity
	30	6	0.87	0.145	0.003≤0.029	conformity
	30	12	1.78	0.148	0.001≤0.030	conformity
	30	20	2.97	0.149	0.002≤0.030	conformity
	30	40	6.02	0.150	0.001≤0.030	conformity
	30	80	12.15	0.152	0.000≤0.030	conformity
	30	150	22.77	0.152	0.001≤0.030	conformity
	30	300	45.72	0.152		*
	30	200	31.40	0.157	0.004≤0.031	conformity
	30	400	61.01	0.153		*

* Blank for the maximum mAs setup and corresponded value setup

<Table 5> Linearity of fifth equipment

Equipment	KV	mAs	Mean (mGy)	mGy /mAs	Linearity	Evaluation
No.5	30	3	0.54	0.181	0.009≤0.035	conformity
	30	6	1.04	0.173	0.028≤0.037	conformity
	30	12	2.41	0.201	0.036≤0.037	conformity
	30	24	3.97	0.165	0.001≤0.033	conformity
	30	47.5	7.82	0.165	0.001≤0.033	conformity
	30	95	15.55	0.164	0.033≤0.036	conformity
	30	190	37.40	0.197	0.032≤0.036	conformity
	30	375	61.69	0.165		*
	30	260	42.35	0.163	0.000≤0.033	conformity
	30	500	81.46	0.163		*

* Blank for the maximum mAs setup and corresponded value setup

All five devices showed appropriate values for the requirements of international standard radiation levels and radiation qualities.

4. Conclusions and discussion

The quality management for diagnosis X-ray generators includes acceptance tests and development tests for manufacturing quality management, and consistency tests for user quality management. The acceptance test is performed for suitability of a device for the specifications when a user and manufacturer adopt a device. The development test is performed to verify the performance conditions of equipment on an ordinary day [9].

The development tests in Korea are performed regularly, from every 3 months to every 3 years, but items have large differences when compared to IEC standards. Post-management for linearity is not done after equipment installation, since the linearity directly related to images is excluded.

The IEC improves international understandings by promoting international cooperation on issues and related matters for standardization, such as the observance confirmation of specifications for electric and electronic fields. There is a goal of reflecting the IEC standard form in the international standards of each country by advising with publications [9]. South Korea has announced IEC advice items by KATS in 1999 [10].

In recent research on the quality management conditions of mammographic devices, DoWan Kim (2010) showed that the inconsistency of devices younger than 10 years old was about 1.7%, but the inconsistency of time-worn devices for about 10 years was very high at about 5.6%[11], in his research on quality management condition comprehension and the future quality management plan of mammographic devices. In addition, advanced research on the performance of devices showed that the performance of devices decreased in smaller hospitals and that time-worn devices need to have inspections more often. Advice was given to perform the overall inspections in the period designated by the manufacturer [12].

According to this research, all linearity was suitable from the results measured for 5 devices of CR and DR mammographic devices. However, these results are considered not to be suitable for the radiation quality requirements of mammographic devices in the entire nation. Therefore, more improved equipment management is needed by including the linearity in quality management items in the future. In addition, plans to apply after modification and supplementation

to the nation in 10-year standards need to be established, since the method of applying current linearity measurement to IEC standards concerns the damage of the device for 10 loads per mAs.

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